

Office Action Summary

Application No.

10/728,056

Applicant(s)

ZERVOS, ANTONIS

Examiner

KENDRA D. CARTER

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-22, 24-29 and 54-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-22, 25-29 and 54-56 is/are rejected.
- 7) ☒ Claim(s) 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 10/369,311 (Patent No. 7,288,546), fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. Particularly, the compounds of formula I, II, III (except when R₁ is NO₂), IV, or more specifically compounds Ucf-102, Ucf-103, and Ucf-104 are not described in the previous application. The only compound disclosed in previous application is compound Ucf-101, or formula III when R₁ is NO₂. Thus, claims 20-22, 25-29 and 54-56 claim priority to the filing date of the present CIP of December 4, 2003. The claim 24 receives the priority of February 20, 2003.

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The Examiner acknowledges the applicant's terminal disclaimer filed November 21, 2008 in response to the office action filed October 30, 2008. Claims 20-22, 24-29 and 54-56 are pending.

In light of the terminal disclaimer filed November 21, 2008, the obvious double patenting rejection over Patent No. 7,288,546 is withdrawn.

Upon further consideration, a new 35 USC 102(a), 103(a) and claim objection is below. Since the new rejections were not made before, the NEW Non-Final office action is below.

Claim Objections

Claim 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 20, 22, 25-28 and 54-55 are rejected under 35 U.S.C. 102(a) as being anticipated by Cilenti et al. (The Journal of Biological Chemistry, March 28, 2003, pp. 11489-11494).

Cilanti et al. teach the characterization of novel and specific inhibitor for the pro-apoptotic protease Omi/HtrA2 (see title), such as ucf-101, -102, -103, and -104 (see Fig. 1 and Fig. 2; addresses claim 20, 25-27, 55 and 56). The inhibition was preformed *in vitro* and monitored with a fluorescence marker such as fluorescein isothiocyanate (FITC; see page 11490, column 1, paragraphs 3 and 6; addresses claims 20, 22, 28, 54 and 55). The compound ucf-101 has been used in *in vivo* tests (see page 11489, column 2, 16-17). Further the compound ucf-101 was found to reduce Omi-induced apoptosis up to 40% (see page; 11493; column 1, paragraph 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21, 29 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cilenti et al. (The Journal of Biological Chemistry, March 28, 2003, pp. 11489-11494) as applied to claims 20, 22, 25-28 and 54-55 above.

The teachings of Cilenti et al. are as applied above.

Cilenti et al. does not specifically teach that the compounds of formula I, II, III (except when R₁ is NO₂), IV, or more specifically compounds Ucf-102, Ucf-103, and Ucf-104 are contacting a cell *in vivo* (claim 21) or monitored for apoptosis of the cell (claims 29 and 56).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Cilenti et al. and contacting the compounds Ucf-102, Ucf-103, and Ucf-104 with a cell *in vivo* (claim 21) or monitored for apoptosis of the cell (claims 29 and 56) because of the following teachings: 1) Cilenti et al. teach that ucf-101 also inhibits Omi/HtrA2 (see Figure 2); 2) the compound ucf-101 has been used in *in vivo* tests (see page 11489, column 2, 16-17); and 3) the compound ucf-101 was found to reduce Omi-induced apoptosis up to 40% (see page; 11493; column 1, paragraph 5). Thus, since all the above compounds inhibit Omi/HtrA2,

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Omi/HtrA2 has been shown to be involved with apoptosis in cells, and ucf-101 was found to successfully reduce apoptosis, one would be motivated to try the other Omi/HtrA2 inhibitors presented in the Cilenti et al. reference.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kendra D Carter/
Examiner, Art Unit 1617

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617